

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 5621-5640**

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b); and its strength and quality differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the quantity, kind, or proportion of alcohol contained therein; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(f)(2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5621. Clarimycin. (F.D.C. No. 41634. S. No. 8-347 P.)

QUANTITY: 880 display cards, each containing 1 btl., at Pittsburgh, Pa.

SHIPPED: 12-9-57, from Jersey City, N.J., by Merritt Corp.

LABEL IN PART: (Btl.) "Contents: 5 Drams Clarimycin Anti-Biotic Acne Lotion * * * Active Ingredients: Neomycin Sulphate, Allantoin."

RESULTS OF INVESTIGATION: The article was regarded as a new drug since it was represented to contain neomycin sulfate and was labeled with directions for use over an extended period of time.

LIBELED: 3-20-58, W. Dist. Pa.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, blackheads, and stubborn skin infections; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 6-20-58. Default—destruction.

5622. Pega Palo. (F.D.C. No. 41618. S. No. 18-288 P.)

QUANTITY: 142 cellophane pkgs. at Salt Lake City, Utah.

SHIPPED: A portion of the article was transported from Chicago, Ill., in January 1957, by Al Cavey and Dave Farrell, partners in the Pega Palo Sales Co., Salt Lake City, Utah, and a portion of the article was shipped from Chicago, Ill., on 3-1-57, by A-1 Import Co.

LIBELED: 3-14-58, Dist. Utah

CHARGE: 502(f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for its used as an aphrodisiac and as a sex rejuvenator, which were the purposes for which the article was intended; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 8-1-58. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5623. R.D.S. laxative herb. (F.D.C. No. 41495. S. No. 14-969 P.)

QUANTITY: 1,386 pkgs. at Louisville, Ky., in possession of R. D. Smith.

SHIPPED: At various times, from Cincinnati, Ohio.

LABEL IN PART: "Net Contents 1 Oz. * * * R.D.S. Laxative Herbs * * *
Active Laxative Ingredients: Senna, Cascara Sagrada. Inactive Ingredients: Saffron, Uva Ursi, Dandelion, Sarsaparilla, Licorice, China Cassia, Anise Seed, Sassafras Bark of Root, Elder Flowers, Cloves and Salicylic Acid * * *
Directions: * * * Prepared for R. D. Smith * * * Zanesville, Ohio."

RESULTS OF INVESTIGATION: R. D. Smith was engaged in vending the product to the public, from a sales booth, on the premises of a retail five-and-dime variety store.

LIBELED: 4-10-58, W. Dist. Ky.

CHARGE: 502(f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use in overcoming worm infestation, indigestion, sour stomach, rheumatism, and for preventing diseases of all types, which were the purposes for which the salesman, R. D. Smith, orally offered the product.

DISPOSITION: 6-27-58. Default—destruction.

5624. Botanical drugs. (F.D.C. No. 41538. S. Nos. 11-870/81 P, 11-883 P, 11-885/97 P, 11-899/914 P, 11-916/38 P.)

QUANTITY: 1,000 lbs. of various crude botanical drugs in cans, drums, cloth or paper bags, and boxes, and an unknown quantity of botanical drugs repackaged into boxes and into 2-, 6-, 12-, and 32-oz. btls. at Port Huron, Mich., in possession of W. H. McConnell. The crude botanical drugs consisted of such articles as *cascara sagrada*, *elm*, *sweetgum*, and *tamarack barks*; *horsetail* and *knottgrasses*; *red clover tops*; *shillingia*, *blue flag*, *burdock*, *yellow dock*, *poke*, *berberis*, *mandrake*, *sassafras*, *bayberry*, *turnip*, *wild gum*, and *button snakeroots*; *mullein*, *buchu*, *damiana*, *strawberry*, *balmony*, and *senna leaves*; *blue vervian*, *chickweed*; *lobelia*, *scouring rush*, and *boneset herbs*; and *palmetto berries*.

SHIPPED: Between 12-15-48 and 11-18-57, from Jersey City, N.J.

*See also No. 5622.